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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/500,324      | 06/28/2004  | Francesco Paolini    | 07552.0031          | 8942             |

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EXAMINER

WIEST, PHILIP R

ART UNIT PAPER NUMBER

3761

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/500,324             | PAOLINI ET AL. ✓    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Phil Wiest             | 3761                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 26-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/12/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. MI2001A002829, filed on December 28, 2001.

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "11a" and "11v" have both been used to designate an expansion chamber. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because reference number 11a does not properly point to the expansion chamber. Applicant is advised to employ the services of a competent patent

draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 26-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Weitzel et al. (US 6561997).

5. With respect to Claims 26-29, Weitzel et al. disclose an apparatus for controlling an extracorporeal blood circuit that is capable of connecting to at least one blood treatment element 48 and a return branch 70 by means of an inlet branch 58 (see Figure 1). The apparatus comprises a sensor/control unit that is capable of "...precise control over fluid flow rate, pressure within the circuit, and temperature of fluid in the circuit" (Column 3, Lines 57-59). Furthermore, the apparatus comprises regulating devices (8 and 34) which are connected to the return branch downstream from the blood treatment element 48. Weitzel et al. further disclose that the regulating device

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comprises a heat exchanger 8 that is connected to the circuit in order to control flow temperature, and a line 16 for conveying a fluid, which reads on Claim 27. The fluid being conveyed is capable of being heated to a temperature lying within a specified range about 37°C, as per instant Claim 28. Regarding Claim 29, the heat exchanger can be "...at least partially surrounding any portion of the intake line" (Column 6, Lines 20-21).

6. With respect to Claim 30, the extracorporeal blood circuit is connected to a pump 52 which conveys fluid along the extracorporeal blood circuit, a line 70 for conveying fluid, and a sensor which detects the operating state of said pump. Regarding Claim 31, Weitzel et al. disclose expansion chambers 62 and 64 and a return branch 70 that is located downstream from the expansion chambers. Examiner interprets that "expansion chambers" are the same as the replacement fluid bags 62 and 64. Said replacement fluid bags serve to "...infuse [fluids] into the conduit 58 with a pump 56 to replace blood volume lost as a waste product 10" (Column 4, Lines 57-58).

7. With respect to Claims 32-35, Weitzel et al. disclose a blood treatment element formed by a filter 48, and at least one expansion chamber 62 and 64. Furthermore, Weitzel et al. disclose that the filter is a hemofilter 48, but that "...and blood treatment device can be used in place of the hemofilter 48. For example, but without limitation, a dialyzer or a plasma filter can be used to separate a filtrate component from the blood" (Column 5, Lines 10-13). Additionally, a dialyzer flowing from dialysis system 194 (see Figure 4) can be used to separate filtrate components from the blood (see Column 5, Line 10-13).

8. With respect to Claims 36 and 37, Weitzel et al. disclose that the control unit regulates the blood temperature in the extracorporeal blood as a function of the blood temperature and the temperature of the body (37°C). Furthermore, Weitzel et al. disclose that the blood temperature is regulated as a function of the difference between the blood temperature and the reference temperature.

9. With respect to Claims 38-43, Weitzel et al. disclose a control method for an extracorporeal blood circuit comprising an access branch 58, a return branch 70 and at least one blood treatment element 48 (see Figure 1). The method comprises measuring and regulating a blood temperature in the extracorporeal blood circuit through the use of circuits that "...will provide tightly controlled pressure, flow, and/or temperature through the circuit" (Column 12, Lines 45-46). The blood temperature is regulated by the heat exchanger 8, which is located downstream from blood treatment element 48.

Regarding Claims 39 and 40, the temperature of the blood is regulated in the heat exchanger 8 as a function of the actual blood temperature and the reference temperature. The heat exchanger 8 "...functions to keep blood at a physiological temperature such that any metabolic functions that the treatment device 20 carries out can be accomplished" (Column 6, Lines 16-19). Thus, the heat exchanger will correct the temperature of the blood according to the difference between the blood and the reference temperature. Heat will be added if this differential is positive, and removed if the differential is negative.

10. With respect to Claims 44-46, Weitzel et al. disclose a method wherein fluid is conveyed along the heat exchanger 8 through the connected tubing. The fluid is heated

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to within a specified range about 37°C. Blood is conveyed through the heat exchanger, as well as the rest of the circuit, by means of a pump. When the pump is not turned on, fluid in the heat exchanger will remain at a temperature equal to the reference temperature. Additionally, the Weitzel et al. discloses that the reference temperature is capable of being varied. The control system allows for "...precise control over fluid flow rate, pressure within the circuit, and temperature of fluid in the circuit" (Column 3, Lines 56-59).

11. With respect to Claims 47-50, Weitzel et al. disclose that the method of conveying fluid is used for a hemodialysis treatment that utilizes a hemofilter. Additionally, Weitzel discloses that any type of blood treatment device such as a dialyzer can be used to separate a filtrate component from the blood. This includes hemofiltration filters and hemodialysis filters through which blood and dialysate flow. See column 5, line 11 of the specification. The extracorporeal blood circuit also comprises expansion chambers 62 and 64 supplied with a replacement fluid (see column 4, lines 56-58).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW  
9/14/2006

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER  
